

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	10/073,863	PEYMAN, GHOLAM A.
	Examiner	Art Unit
	Humera N. Sheikh	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 27 January 2006.
2.  The allowed claim(s) is/are 1-4, 10, 13-32 and 34-40.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7.  The drawing filed 02/14/2002 is accepted by the Examiner.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 4/18/06.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

*Humera N. Sheikh  
HUMERA N. SHEIKH  
PATENT EXAMINER  
TC4600*

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Appeal Brief filed 01/27/06 and the Notice of Appeal and the request for extension of time (1 month-granted), both filed 07/21/05 is acknowledged.

Claims 1, 4-10, 13-32 and 34-40 are pending in this action. Claims 1, 10, 20, 23, 28 and 36 have been amended herein. Claims 2, 3, 11, 12 and 33 have previously been cancelled. Claims 1, 4-10, 13-32 and 34-40 are allowed.

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Garrett V. Davis on April 18, 2006.

The application has been amended as follows:

### **In the Abstract:**

The words 'of th Disclosur' have been deleted.

**In the Claims:**

In claim 1, line 4, the term “*including*” has been replaced with “**comprising**”.

In claim 1, line 6, before the term “*applying*”, the phrase **“introducing a second dye encapsulated in a second liposome where the second dye is releasable at a temperature at or above the protein denaturization temperature”** has been **added**.

In claim 10, line 6, after the phrase “*to 49°C, and*”, the phrase **““introducing a second dye encapsulated in a second liposome where the second dye is releasable at a temperature at or above the protein denaturization temperature”** has been **added**.

In claim 20, lines 1-3, the limitation **“further comprising the step of introducing a second fluorescent dye encapsulated in a second heat sensitive liposome into said bloodstream of said animal”** has been deleted and replaced with the term **“wherein”**.

In claim 23, line 4, the term “*including*” has been replaced with “**comprising**”.

In claim 28, line 4, the term “*including*” has been replaced with “**comprising**”.

In claim 36, lines 1-3, the limitation **“further comprising the step of introducing a second liposome containing a second fluorescent dye into the bloodstream of said animal to flow through said target site”** has been **deleted**.

***Allowable Subject Matter***

Claims 1, 4-10, 13-32 and 34-40 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Zeimer – U.S. Patent No. 5,935,942; Khoobehi *et al.* – U.S. Patent No. 5,976,502; Rahman – U.S. Patent No. 3,993,754) does not disclose nor teach the instant method of hyperthermally treating tissue in an animal that comprises the steps of: (1) releasing a fluorescent dye encapsulated within a heat sensitive liposome at a temperature of about 45<sup>0</sup>C to about 49<sup>0</sup>C and; (2) applying a heat source to a target site and hyperthermally heating to a temperature of at least 47<sup>0</sup>C and; (3) hyperthermally treating tissue to kill cells without denaturing proteins in the tissue. The prior art fails to disclose or teach such a method of hyperthermally treating tissue that comprises releasing a fluorescent dye at the instantly claimed temperature range (about 45<sup>0</sup>C to about 49<sup>0</sup>C) and subsequently heating tissue at the instantly claimed temperature (at least 47<sup>0</sup>C). Additionally, the prior art fails to disclose or teach hyperthermally treating tissue to kill cells at a temperature, which is below the protein denaturation temperature. The prior art is deficient multiple fold in that it provides no disclosure or teaching of hyperthermally treating tissue using the temperatures claimed and provides no teaching of heating tissue for ample time to result in killing of the cells. Applicants have demonstrated that the instantly claimed temperatures and temperature ranges are crucial. Particularly, protein denaturation occurs rapidly at 60<sup>0</sup>C. Thus, the temperatures instantly claimed herein, which are maintained below 60<sup>0</sup>C, do not result in proteins becoming denatured.

In contrast, the prior art (Zeimer '942) teaches a method of chemically (not hyperthermally) and non-invasively treating tissue and cells to cause occlusion of blood vessels. Zeimer's method utilizes chemical, non-thermal means of occluding vessels and is not drawn to thermal treatment of tissue. To prevent damage to tissue (which is opposite of killing cells as instantly claimed) Zeimer heats blood vessels to approximately 41°C. Zeimer specifically discloses that heating to a temperature of about 41°C does not thermally treat tissues or cells and does not cause substantial damage to vasculature. This is in stark contrast to the instant hyperthermal method of treating tissue which uses much higher temperatures in order to intentionally provide for the death of cells. Additionally, the Khoobehi ('502) and Rahman patents ('754) do not disclose, teach or suggest a method of hyperthermally treating tissue by employing temperatures as presently claimed and heating for a sufficient time to kill cells without denaturing proteins.

The instant invention demonstrates significant improvement over prior art formulations in that the method of the invention provides for visual temperature detection and allows for the control of hyperthermal treatment within a temperature range sufficient to kill cells without excessive heating that can cause denaturing of proteins.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

April 24, 2006

*Humera N. Sheikh*

TE-1600

*hns*